

*5/2/07*

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### Documents

- **Atrial defibrillator tackles matter of the heart**  
*Mark A Gottschalk. Design News. Boston:Jun 9, 1997. Vol. 52, Iss. 11, p. 65-66 (2 pp.)*

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**Ventritex implantable defibrillator approved for commercial release**  
*Fischer, Frank M. Business Wire. New York:May 03, 1993. Section 1, p. 1*

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**Cardiac Resynchronization Pacing Therapy**  
*Cash Casey, Bradley P. Knight. Cardiology. Basel:2004. Vol. 101, Iss. 1-3, p. 72-8*

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**Permanently Implantable Diagnostic Computerized Devices: Where Is the Regulatory Bar?**  
*Mitchell W Krucoff. Journal of Electrocardiology.: Research and Technology Transfer in Computerized... New York:2004. Vol. 37, p. 68-70 (3 pp.)*

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**Cardiac Resynchronization Therapy with or without an Implantable Defibrillator: Only Indicated When Everything Else has Failed?**  
*J. Ghosh, Gerry Kaye, J.G.F. Cleland. Cardiac Electrophysiology Review. Boston:Dec 2003. Vol. 7, Iss. 4, p. 421-9*

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**Advances in devices for cardiac resynchronization in heart failure**

*Chu-Pak Lau, Serge Barold, Hung-Fat Tse, Kathy Lai-Fun Lee, et al.* **Journal of Interventional Cardiac Electrophysiology**. Norwell:Oct 2003. Vol. 9, Iss. 2, p. 167

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**Implantable diagnostic monitoring devices for evaluation of syncope, and tachy- and brady-arrhythmias**

*David G Benditt, Cengiz Ermis, Scott Pham, Laura Hiltner, et al.* **Journal of Interventional Cardiac Electrophysiology**. Norwell:Oct 2003. Vol. 9, Iss. 2, p. 137

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**Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: The MIRACLE ICD trial**

*James B Young, William T Abraham, Andrew L Smith, Angel R Leon, et al.* **JAMA**. Chicago:May 28, 2003. Vol. 289, Iss. 20, p. 2685-94 (10 pp.)

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**New pacing technologies for heart failure**

*Anthony W C Chow, Rebecca E Lane, Martin R Cowie.* **British Medical Journal**. (International Edition). London:May 17, 2003. Vol. 326, Iss. 7398, p. 1073-7 (5 pp.)

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**Quality of Life and Psychological Impact of Implantable Cardioverter Defibrillators: Focus on Randomized Controlled Trial Data**

*Michael John McCready, Derek V. Exner.* **Cardiac Electrophysiology Review**. Boston:Jan 2003. Vol. 7, Iss. 1, p. 63

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Document 1 of 10

**DESIGN NEWS**

**Atrial defibrillator tackles matter of the heart**

Mark A Gottschalk. **Design News**. Boston:Jun 9, 1997. Vol. 52, Iss. 11, p. 65-66 (2 pp.)

#### Abstract (Summary)

InControl's Metrix, the first implantable atrial defibrillator, is in clinical trials worldwide. The device was more than five years in development.

#### Indexing (document details)

**Subjects:** Medical equipment, Transplants & implants, Cardiovascular disease  
**Companies:** InControl Systems Inc  
**Author(s):** Mark A Gottschalk  
**Document types:** News  
**Publication title:** Design News. Boston: Jun 9, 1997. Vol. 52, Iss. 11; pg. 65, 2 pgs  
**Source type:** Periodical  
**ISSN:** 00119407  
**ProQuest document ID:** 12418808  
**Text Word Count** 1191  
**Document URL:** <http://proquest.umi.com/pqdweb?did=12418808&Fmt=4&clientId=19649&RQT=309&VName=PQD>

Document 2 of 10



#### Ventritex implantable defibrillator approved for commercial release

Fischer, Frank M. **Business Wire**. New York:May 03, 1993. Section 1, p. 1

#### Abstract (Summary)

Ventritex Inc. (NASDAQ:VNTX) reported Friday that the U.S. Food and Drug Administration (FDA) approved its Cadence implantable defibrillator system for commercial release. This highly sophisticated medical device is designed to treat life-threatening abnormally fast heart rhythms called tachyarrhythmias and offers features not available in any other systems. The new device is the first commercially released product of Sunnyvale based Ventritex Inc., founded in 1985. Sales of the Cadence system have been restricted during its clinical trials which began with the system's initial implant in 1989. The company has been preparing for the introduction of the Cadence during recent months through expansion of its production, clinical engineering and sales capabilities. Commercial distribution will begin immediately. (excerpt)

#### Indexing (document details)

**Subjects:** Regulatory agencies, Product introduction, Pacific, Medical equipment, Instrumentation industry  
**Classification Codes** 8650, 7500  
**Locations:** US, Sunnyvale, CA  
**Companies:** Ventritex Inc(Ticker:VNTX, Sic:3841 )

**Author(s):** Fischer, Frank M  
**Publication title:** Business Wire. New York: May 03, 1993. Sec. 1. pg. 1  
**Publication Section:** 1  
**Source type:** Wire Feed  
**ProQuest document ID:** 7330306  
**Text Word Count:** 553  
**Document URL:** <http://proquest.umi.com/pqdweb?did=7330306&Fmt=3&clientId=19649&RQT=309&VName=PQD>

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#### Document 3 of 10

#### **Cardiac Resynchronization Pacing Therapy**

Cash Casey, Bradley P. Knight. **Cardiology**. Basel:2004. Vol. 101, Iss. 1-3, p. 72-8

#### **Abstract (Summary)**

Approximately one third of patients with congestive heart failure and systolic dysfunction have an intraventricular conduction delay that is manifested as a QRS duration >120 ms. An intraventricular conduction delay adversely affects ventricular performance by causing dyssynchrony in ventricular activation. When ventricular dyssynchrony is present, simultaneous left and right ventricular pacing or cardiac resynchronization therapy can improve ventricular synchrony. This can lead to an improvement in hemodynamics, ventricular remodeling, mitral regurgitation, exercise capacity and quality of life. Candidates for cardiac resynchronization therapy include patients with advanced congestive heart failure that is refractory to medical therapy, a QRS duration >130 ms, left ventricular ejection fraction <0.35 and sinus rhythm. Because patients who are candidates for biventricular pacing are at high risk of sudden death, they should be considered for implantation of a biventricular pacing device that also provides defibrillation therapy. This paper reviews biventricular pacing for congestive heart failure, including results of acute hemodynamic studies and randomized clinical trials, patient and device selection, and procedural issues.

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#### **Indexing (document details)**

**MeSH subjects:** Defibrillators, Implantable, Electrocardiography, Heart Failure, Congestive -- physiopathology, Heart Failure, Congestive -- therapy, Hemodynamic Processes -- physiology, Humans, Myocardial Contraction -- physiology, Pacemaker, Artificial, Prosthesis Design, Randomized Controlled Trials, Ventricular Dysfunction, Left -- physiopathology, Ventricular Dysfunction, Left -- therapy, Ventricular Dysfunction, Right -- physiopathology, Ventricular Dysfunction, Right -- therapy  
**Author(s):** Cash Casey, Bradley P. Knight  
**Document types:** Journal Article  
**Publication title:** Cardiology. Basel: 2004. Vol. 101, Iss. 1-3; pg. 72  
**Source type:** Periodical  
**ISSN:** 00086312  
**ProQuest document ID:** 677161421  
**Text Word Count:** 4815  
**Document URL:** <http://proquest.umi.com/pqdweb?did=677161421&Fmt=10&clientId=19649&RQT=309&VName=PQD>

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## Document 4 of 10

**Permanently Implantable Diagnostic Computerized Devices: Where Is the Regulatory Bar?**

*Mitchell W Krucoff. Journal of Electrocardiology: Research and Technology Transfer in Computerized... New York:2004. Vol. 37, p. 68-70 (3 pp.)*

Document URL: <http://proquest.umi.com/pqdweb?did=744975411&Fmt=3&clientId=19649&RQT=309&VName=PQD>

## Document 5 of 10

**Cardiac Resynchronization Therapy with or without an Implantable Defibrillator: Only Indicated When Everything Else has Failed?**

*J. Ghosh, Gerry Kaye, J.G.F. Cleland. Cardiac Electrophysiology Review. Boston:Dec 2003. Vol. 7, Iss. 4, p. 421-9*

**Abstract (Summary)**

Cardiac resynchronization therapy (CRT) is potentially an important new treatment for patients with heart failure due to left ventricular systolic dysfunction and cardiac dyssynchrony. There is growing evidence that CRT can improve symptoms although it is possible that similar benefits could be obtained by skillful manipulation of pharmacological therapy. There is also preliminary but inconclusive evidence to suggest that CRT alone or in synergy with an implantable cardiac defibrillator (ICD) may reduce morbidity and mortality. However, fashion is in danger of overtaking facts and it is important to ensure that benefits are not only statistically proven but clinically meaningful and cost-effective. Optimal timing of intervention and patient selection will be essential to ensure that treatment is deployed efficiently. If CRT with or without ICD becomes part of mainstream therapy for heart failure this will have far-reaching consequences for heart failure management. Implantation is a skilled and often time-consuming procedure. Long-term management of both CRT and ICD is likely to provide challenges in terms of lead technology, pacing thresholds and device management. Heart failure physicians will have to learn new skills and collaborate more closely with electrophysiologists. Such developments, in addition to the need for complex pharmacological interventions will accelerate the move away from general practice and towards specialist care for this most common of malignant diseases. If CRT does reduce mortality, it will graduate from an adjunctive therapy which could be used to an essential one that should be used as part of routine therapy for appropriate patients. Currently, CRT is a symptomatic therapy for patients with severe heart failure resistant to intensive pharmacological therapy delivered by a heart failure specialist.

**Indexing (document details)**

**MeSH subjects:** Arrhythmia -- therapy, Cardiac Pacing, Artificial, Combined Modality Therapy, Defibrillators, Implantable, Heart Failure, Congestive -- therapy, Hospitalization, Humans, Pacemaker, Artificial, Treatment Failure, Ventricular Dysfunction, Left -- therapy

**Author(s):** J. Ghosh, Gerry Kaye, J.G.F. Cleland

**Document types:** Journal Article

**Publication title:** Cardiac Electrophysiology Review. Boston: Dec 2003. Vol. 7, Iss. 4; pg. 421

**Source type:** Periodical

**ISSN:** 13852264

**ProQuest document ID:** 623820241

**Text Word Count** 6600

**Document URL:** <http://proquest.umi.com/pqdweb?did=623820241&Fmt=10&clientId=19649&RQT=309&VName=PQD>

## Document 6 of 10

**Advances in devices for cardiac resynchronization in heart failure**

*Chu-Pak Lau, Serge Barold, Hung-Fat Tse, Kathy Lai-Fun Lee, et al. Journal of Interventional Cardiac Electrophysiology. Norwell:Oct 2003. Vol. 9, Iss. 2, p. 167*

Document URL: <http://proquest.umi.com/pqdweb?did=462982941&Fmt=3&clientId=19649&RQT=309&VName=PQD>

## Document 7 of 10

**Implantable diagnostic monitoring devices for evaluation of syncope, and tachy- and brady-arrhythmias**

*David G Benditt, Cengiz Ermis, Scott Pham, Laura Hiltner, et al. Journal of Interventional Cardiac Electrophysiology. Norwell:Oct 2003. Vol. 9, Iss. 2, p. 137*

Document URL: <http://proquest.umi.com/pqdweb?did=462982781&Fmt=3&clientId=19649&RQT=309&VName=PQD>

## Document 8 of 10

**Combined cardiac resynchronization and implantable cardioversion defibrillation in advanced chronic heart failure: The MIRACLE ICD trial**

*James B Young, William T Abraham, Andrew L Smith, Angel R Leon, et al. JAMA. Chicago:May 28, 2003. Vol. 289, Iss. 20, p. 2685-94 (10 pp.)*

**Abstract (Summary)**

Context Cardiac resynchronization therapy (CRT) through biventricular pacing is an effective treatment for heart failure (HF) with a wide QRS; however, the outcomes of patients requiring CRT and implantable cardioverter defibrillator (ICD) therapy are unknown. Objective To examine the efficacy and safety of combined CRT and ICD therapy in patients with New York Heart Association (NYHA) class III or IV congestive HF despite appropriate medical management. Design, Setting, and Participants Randomized, double-blind, parallel-- controlled trial conducted from October 1, 1999, to August 31, 2001, of 369 patients with left ventricular ejection fraction of 35% or less, QRS duration of 130 ms, at high risk of life-threatening ventricular arrhythmias, and in NYHA class III (n=328) or IV (n=41) despite optimized medical treatment. Interventions Of 369 randomized patients who received devices with combined CRT and ICD capabilities, 182 were controls (ICD activated, CRT off) and 187 were in the CRT group (ICD activated, CRT on). Main Outcome Measures The primary double-blind study end points were changes between baseline and 6 months in quality of life, functional class, and distance covered during a 6-minute walk. Additional outcome measures included changes in exercise capacity, plasma neurohormones, left ventricular function, and overall HF status. Survival, incidence of ventricular arrhythmias, and rates of hospitalization were also compared. Results At 6 months, patients assigned to CRT had a greater improvement in median (95% confidence interval) quality of life score (-17.5 [-21 to -14] vs -11.0 [-16 to -7], P=.02) and functional class P P to [-1 [ to-1] vs 0 [-1 to 0], P=.007) than controls but were no different in the change in distance walked in 6 minutes (55 m [44-79] vs 53 m [43-75], P=.36). Peak oxygen consumption increased by 1.1 mL/kg per minute (0.7-1.6) in the CRT group vs 0.1 mL/kg per minute (-0.1 to 0.8) in controls (P=.04), although treadmill exercise duration increased by 56 seconds (30-79) in the CRT group and decreased by 11 seconds (-55 to 12) in controls (P<.001). No significant differences were observed in changes in left ventricular size or function, overall HF status, survival, and rates of hospitalization. No proarrhythmia was observed and arrhythmia termination capabilities were not impaired. Conclusions Cardiac resynchronization improved quality of life, functional status, and exercise capacity in patients with moderate to severe HF, a wide QRS interval, and life-threatening arrhythmias. These improvements occurred in the context of underlying appropriate medical management without proarrhythmia or compromised ICD function.

**Indexing (document details)**

**Subjects:** Cardiovascular disease

**MeSH subjects:** Aged, Cardiac Pacing, Artificial, Cross-Over Studies, Defibrillators, Implantable, Double-Blind Method, Electric Countershock, Exercise Tolerance, Female, Heart Failure, Congestive -- physiopathology, Heart Failure, Congestive -- therapy, Heart Function Tests, Humans, Male, Pacemaker, Artificial, Postoperative Complications, Quality of Life, Research Support, Non-U.S. Gov't, Survival Analysis, Tachycardia, Ventricular, Ventricular Dysfunction, Left, Ventricular Fibrillation

**Author(s):** James B Young, William T Abraham, Andrew L Smith, Angel R Leon, et al

**Document types:** Feature

**Publication title:** JAMA. Chicago: May 28, 2003. Vol. 289, Iss. 20; pg. 2685, 10 pgs

**Source type:** Periodical

**ISSN:** 00987484

**ProQuest document ID:** 344135831

**Text Word Count** 7569

**Document URL:** <http://proquest.umi.com/pqdweb?did=344135831&Fmt=18&clientId=19649&RQT=309&VName=PQD>

**Document 9 of 10****New pacing technologies for heart failure**

*Anthony W C Chow, Rebecca E Lane, Martin R Cowie.* **British Medical Journal.** (International Edition). London: May 17, 2003. Vol. 326, Iss. 7398, p. 1073-7 (5 pp.)

**Abstract (Summary)**

Clinical trials have shown that biventricular pacing is effective in the treatment of heart failure patients with left bundle branch block (table). Several randomised controlled clinical trials have compared biventricular pacing with medical treatment on its own.

**Indexing (document details)**

**Subjects:** Heart failure, Clinical outcomes, Medical technology, Defibrillators

**MeSH subjects:** Cardiac Output, Low -- therapy, Cardiac Pacing, Artificial -- adverse effects, Cardiac Pacing, Artificial -- methods, Cardiac Pacing, Artificial -- trends, Chronic Disease, Clinical Trials, Human, Pacemaker, Artificial -- adverse effects, Pacemaker, Artificial -- trends, Support, Non-U.S. Gov't

**Author(s):** Anthony W C Chow, Rebecca E Lane, Martin R Cowie

**Document types:** Feature

**Publication title:** British Medical Journal. (International edition). London: May 17, 2003. Vol. 326, Iss. 7398; pg. 1073, 5 pgs

**Source type:** Periodical

**ISSN:** 09598146

**ProQuest document ID:** 347551391

**Text Word Count** 3506

**Document URL:** <http://proquest.umi.com/pqdweb?did=347551391&Fmt=4&clientId=19649&RQT=309&VName=PQD>

Document 10 of 10

**Quality of Life and Psychological Impact of Implantable Cardioverter Defibrillators: Focus on Randomized Controlled Trial Data**

Michael John McCready, Derek V. Exner. *Cardiac Electrophysiology Review*. Boston: Jan 2003. Vol. 7, Iss. 1, p. 63

**Abstract (Summary)**

The defibrillator has been shown to reduce mortality in a number of patient groups with cardiac disease. Given the number of individuals with defibrillators it is important to understand the influence of these devices quality of life. Advances have led to smaller devices, less-invasive implantation, and more refined arrhythmia management. The potential impact of the defibrillator on quality of life continues to evolve with these advances. This review discusses the impact of the defibrillator on psychological well-being and quality of life, particularly the results of recent large randomized trials.

Observational studies evaluating the relationship between defibrillator implantation and quality of life have not shown consistent results, but recent data from randomized trials provide important insights. Among patients who have survived life-threatening arrhythmias the defibrillator is associated with similar or perhaps superior quality of life versus antiarrhythmic drug therapy. However, patients who experience shocks have poorer quality of life versus those who do not. The reduction in quality of life with multiple shocks is of similar magnitude to serious side effects from antiarrhythmic drugs. While patients with defibrillators are at risk for poor quality of life.

The advantages and disadvantages of defibrillator therapy versus amiodarone or usual medical care should be discussed with patients in whom a defibrillator is recommended. Those undergoing defibrillator implantation should be advised that adverse events and/or multiple shocks occur in a minority of patients, but may lead to reduced quality of life and it is vital that support resources be made available for these individuals.

**Indexing (document details)**

**Author(s):** Michael John McCready, Derek V. Exner  
**Publication title:** Cardiac Electrophysiology Review. Boston: Jan 2003. Vol. 7, Iss. 1; pg. 63  
**Source type:** Periodical  
**ISSN:** 13852264  
**ProQuest document ID:** 345612511  
**Text Word Count** 5838  
**Document URL:** <http://proquest.umi.com/pqdweb?did=345612511&Fmt=10&clientId=19649&RQT=309&VName=PQD>

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| S27 | 7   | (S19 or S20) and S5   | USPAT | OR | OFF | 2007/11/14 08:48 |
| S28 | 3   | (S19 or S20) and S6   | USPAT | OR | OFF | 2007/11/14 08:43 |
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